Monochlorotoluenes - Environmental Defense Comments

(Submitted via Internet 8/5/02)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Monochlorotoluenes.

In its cover letter for this submission, Occidental Chemical Corporation states that it had originally committed to sponsor three substances:

* Toluene, p-chloro (CAS 106-43-4)
* Benzene, 1-chloro-2-methyl (CAS 95-49-8) (also known as o-chlorotoluene)
* Benzene, chloromethyl- (CAS 25168-05-2) (also known as mixed monochlorotoluenes)

Occidental also states that it ceased manufacture of these compounds in September 2001, and that its contractor preparing the robust summary/test plans for these three substances ceased work at that time. Occidental states that its submission is comprised of the material gathered by the contractor “in the form in which it existed at the time” the contractor ceased work.

This truncated process may explain some of the problems with the materials as submitted, which do not constitute a completed test plan/robust summary. It appears that Occidental does not intend to complete the robust summary/test plan, much less to carry out any additional testing that may be needed. As a result, either another company should take over sponsorship of these substances, or they should be deemed no longer to be sponsored.

We have proceeded to review the draft materials as submitted. Our comments on those materials appear below, but may well change if additional information were to be provided. Although there is a conclusory statement that the chemicals should be treated as a category, no specific justification is provided, so it is not possible to evaluate the adequacy of this claim at present.

General Comment. The test plan concludes that " there is sufficient information to assess the risks posed by monochlorotoluenes in their specific utilization niches". We disagree with this statement in two ways. First, information presented in the test plan and summaries do not fulfill requirements of the HPV program as there are numerous data gaps and there is a clear need for additional toxicity information. Second, we cannot evaluate any statement concerning utilization niches as no information was provided regarding uses, environmental releases or potential for human exposures in the home, workplace or general environment.

The following are specific comments regarding apparent needs for additional toxicity information.

1. Genetic toxicity. In vitro genetic toxicity tests were conducted on p-chlorotoluene but not o-chlorotoluene. Since the test plan did not attempt to justify establishment of a category for the three CAS numbers, we recommend that in vitro tests be conducted on o-chlorotoluene. Both o-chlorotoluene and p-chlorotoluene are hydroxylated but the hydroxylation sites are different for the two chemicals and this could cause differences in mutagenic activity.

2. Repeat dose studies. The test plan states that repeat dose studies were conducted on both o- and p-chlorotoluene. However, upon review of the relevant robust summaries (which may well be incomplete as noted above) it appears that a) the 14-day subacute study of p-chlorotoluene in rats appears to simply reaffirm results from the acute toxicity studies and it cannot be considered a valid repeat dose study; b) the 90-day subacute study in rats also only serves to reaffirm the acute toxicity data as no information was given on histological analyses and the results merely state that the monochlorotoluene possesses low to moderate acute toxicity; and c) the mixture studies in dogs and rats are more complete but such a mixture

study may be inadequate to evaluate repeat dose toxicity for the individual congeners. Unless additional information is available, it would appear that repeat dose studies should conducted on both o- and p-chlorotoluene.

3. Reproductive and developmental toxicity. No reproductive studies are available on either o-or p-chlorotoluene. A developmental toxicity study was claimed to have been conducted on o-chlorotoluene but no information was given on doses, control groups, or route of administration and the results section was blank. Obviously, this section was not completed, making it impossible to determine whether additional studies on developmental toxicity are needed. If so, it may be appropriate to conduct a combined repeat dose/reproduction/ development study on o- and p-chlorotoluene.

Thank you for this opportunity to comment.

George Lucier, Ph.D.
Consulting Toxicologist, Environmental Defense

Karen Florini
Senior Attorney, Environmental Defense